

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P. et al.,	)	
	)	
Plaintiffs,	)	Consolidated Civil Action No. 10-5954-WHW-CLW
	)	
v.	)	<b>MOTION RETURN DATE: DECEMBER 21, 2015</b>
	)	
LUPIN LIMITED et al.,	)	<i>Document Electronically Filed</i>
	)	
Defendants.	)	
	)	

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**BRIEF IN SUPPORT OF JANSSEN'S AND MYLAN'S JOINT MOTION FOR AN  
INDICATIVE RULING PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE  
62.1 ON A MOTION TO MODIFY THE COURT'S FINAL JUDGMENT ORDER**

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John E. Flaherty (jflaherty@mccarter.com)  
**MCCARTER & ENGLISH LLP**  
 100 Mulberry Street  
 Four Gateway Center  
 Newark, New Jersey 07102  
 Telephone: (973) 639-7903

James E. Cecchi (JCecchi@carellabyrne.com)  
 Melissa E. Flax (mflax@carellabyrne.com)  
**CARELLA, BYRNE, CECCHI, OLSTEIN,  
 BRODY & AGNELLO, P.C.**  
 5 Becker Farm Road  
 Roseland, New Jersey 07068-1739  
 Telephone: (973) 994-1700

*Of Counsel*

Gregory L. Diskant (gldiskant@pbwt.com)  
 Eugene M. Gelernter  
 (emgelernter@pbwt.com)  
 Steven A. Zalesin (sazalesin@pbwt.com)  
 Irena Royzman (iroyzman@pbwt.com)  
**PATTERSON BELKNAP WEBB & TYLER LLP**  
 1133 Avenue of the Americas  
 New York, New York 10036  
 Telephone: (212) 336-2000

*Attorneys for Plaintiffs/Counterclaim-  
 Defendants Janssen Products, L.P. and  
 Janssen Sciences Ireland UC*

*Of Counsel*

William A. Rakoczy  
 (wrakoczy@rmmslegal.com)  
 Deanne M. Mazzochi  
 (dmazzochi@rmmslegal.com)  
 Amy D. Brody (abrody@rmmslegal.com)  
 Tara M. Raghavan  
 (traghavan@rmmslegal.com)  
**RAKOCZY MOLINO MAZZOCHI SIWIK LLP**  
 6 West Hubbard Street, Suite 500  
 Chicago, Illinois 60654  
 Telephone: (312) 222-6301

*Attorneys for Defendants/Counterclaim-  
 Plaintiffs Mylan Pharmaceuticals Inc. and  
 Mylan Inc.*

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## **INTRODUCTION**

Pursuant to Federal Rule of Civil Procedure 62.1, Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, “Plaintiffs”) and Defendants Mylan Pharmaceuticals Inc. (“Mylan Pharms”) and Mylan Inc. (collectively, “Mylan”) jointly move the Court for an “indicative ruling” on a motion under Federal Rule of Civil Procedure 60(b) to modify the injunctive provisions of the Court’s final judgment Order and trial Opinion entered on August 14, 2014 (“Final Judgment Order”) (ECF No. 944), as they relate to Mylan in light of the recent settlement of this action.

On November 9, 2015, after full briefing of Mylan’s appeal from the Final Judgment and before oral argument in that appeal, Plaintiffs and Mylan executed a Settlement Agreement and a License Agreement (collectively, the “Agreement”) fully resolving, as relevant here, the claims and counterclaims asserted in this action relevant to Mylan and U.S. Patent No. 7,772,411 (“the ‘411 patent”), subject to and conditioned upon modification of the Final Judgment Order as described herein.<sup>1</sup> The terms of the Agreement are confidential, but as a general matter, the Agreement grants Mylan a license to market the proposed products that are the subject of Mylan Pharms’ Abbreviated New Drug Application No. 202136 (“Mylan Pharms’ ANDA Products”) on a specified date before the expiration of the ‘411 patent. The parties also agreed to approach this Court seeking a modification of certain provisions of the Final Judgment Order as they relate to Mylan. Specifically, the parties respectfully request that the Court modify the Final Judgment Order (ECF No. 944) and the Court’s trial Opinion (ECF No. 943) underlying that Order, which enjoins Mylan from, among other things, selling or offering for sale Mylan Pharms’ ANDA

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<sup>1</sup> This request for relief does not relate to the injunction provisions relevant to Defendants Lupin Limited and Lupin Pharmaceuticals Inc. Rather, the requested relief herein only relates to the proceedings as relevant to Mylan and the ‘411 patent.

Products until expiration of the '411 patent, to allow Mylan to engage in such activities pursuant to the terms of the Agreement. The Final Judgment Order and its underlying findings and conclusions of law would otherwise remain intact. Amending the Final Judgment Order and Opinion in this manner is necessary for Mylan to exercise its license rights under the Agreement and is an express condition of the Agreement's continued effect.

This matter is currently pending on appeal in the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"). Immediately following execution of the Agreement, the parties jointly sought and obtained a stay of further appellate proceedings.

Pursuant to Federal Rule of Civil Procedure 62.1, a district court, while divested of jurisdiction by a pending appeal, *see, e.g., Venen v. Sweet*, 758 F.2d 117, 120 (3d Cir. 1985), may nonetheless provide an "indicative ruling" stating that it would grant a motion under Federal Rule of Civil Procedure 60(b) if the appellate court remands for that purpose pursuant to Federal Rule of Appellate Procedure 12.1. Such an "indicative ruling" — to the effect that this Court would modify its Final Judgment Order to amend the injunctive relief provisions if the Federal Circuit should remand this case — is the precise relief the parties seek here; it is also the very type of relief for which Federal Rule of Civil Procedure 62.1 was enacted. *See* FED. R. CIV. P. 62.1, 2009 Advisory Committee Note. If this Court grants this Motion, the parties would then notify the Federal Circuit pursuant to Federal Rule of Appellate Procedure 12.1 and request that the Federal Circuit remand this action for entry by the Court of a modified Final Judgment Order.

### **BACKGROUND**

Plaintiffs filed the underlying consolidated litigation (Civil Action No. 10-cv-5954) against Mylan on November 15, 2010, asserting infringement of a patent not subject to this

Motion. On January 10, 2013, the Court granted Plaintiffs' motion to file an amended complaint to assert infringement of the '411 patent. (ECF No. 263). Plaintiffs filed their Amended Complaint on January 18, 2013. (ECF No. 267). The Court conducted trial proceedings in this consolidated litigation between March 18 and April 9, 2014. During those trial proceedings, Janssen only asserted the '411 patent against Mylan. On August 14, 2014, this Court entered final judgment in favor of Plaintiffs. (ECF Nos. 943, 944). As relevant here, Paragraph 4 of the Final Judgment Order enjoins:

Mylan and its officers, directors, employees, agents, successors, affiliates, and assigns, and all persons and entities acting in concert or participation with them . . . until the expiration of the '411 Patent from using, selling, or offering for sale in the United States, or importing into the United States, the darunavir tablets described in Mylan's ANDA, ANDA 202136, or any darunavir product made by any colorable variation of the process used to make Mylan's ANDA 202136 product.

(ECF No. 944 at 2, ¶ 4). The first paragraph on page 93 of the underlying trial Opinion, entered on August 14, 2014, states that "[t]he Court . . . grants a permanent injunction enjoining Mylan from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in Mylan's ANDA or made by a process that is a colorable variation of the process claimed in the '411 Patent, until after the expiration date of the '411 Patent." (ECF No. 943 at 93). Mylan appealed this Court's final judgment to the Federal Circuit, where the action is fully briefed and currently pending.

On November 9, 2015, the parties settled this action, conditioned upon modification of the Final Judgment Order as described here. The Agreement will permit the manufacture and sale of Mylan Pharms' ANDA Products on a specified date prior to expiration of the '411 patent. To give practical effect to the terms of the Agreement, however, Mylan must be free to market Mylan Pharms' ANDA Products consistent with the terms of the Agreement. Effectuation of the

parties' Agreement, therefore, requires that the Final Judgment Order be modified to amend the injunction entered against Mylan, which, *inter alia*, enjoins Mylan from manufacturing and selling Mylan's ANDA Products during the term of the '411 patent. A copy of the parties' proposed Order Entering Modified Judgement is attached as Exhibit A.

### **ARGUMENT**

#### **I. Partial Relief from the Opinion and Final Judgment Order May Be Granted Under Federal Rule of Civil Procedure 60(b) to Give Effect to the Parties' Settlement.**

Federal Rule of Civil Procedure 60(b) provides that “[o]n motion and just terms, the court may relieve a party . . . from a final judgment, order, or proceeding.” Several reasons justify relief under Rule 60(b), two of which apply here. *See* FED. R. CIV. P. 60(b)(5), (6).

Under Rule 60(b)(5), a district court may modify a final judgment where “applying [the final judgment] prospectively is no longer equitable.” FED. R. CIV. P. 60(b)(5). Parties seeking modification of a final judgment pursuant to this provision must demonstrate that a significant change in circumstances warrants revision of the judgment. *Rufo v. Inmates of Suffolk Cty. Jail*, 502 U.S. 367, 383 (1992). Once the movant has met that burden, the Court should then “consider whether the proposed modification is suitably tailored to the changed circumstance.” *Id.*; *Agostini v. Felton*, 521 U.S. 203, 215 (1997) (applying *Rufo* standards to modifications of injunctions in final judgments). Here, continued application of the injunction against Mylan in the Final Judgment Order would no longer be equitable: it would defeat the key feature of the parties' settlement—i.e., the grant of a license to Mylan. Such a result would be in direct

contravention of the parties' intent as well as the strong policy favoring settlement.<sup>2</sup> For this reason, the Agreement provides that it will not be effective, and the appeal proceedings will proceed, if the Opinion and Order are not modified in the manner requested herein.

The relief requested herein is "suitably tailored to the changed circumstance," *Rufo*, 502 U.S. at 383: that is, the settlement as reflected in the Agreement. The parties seek to modify the Final Judgment Order in a limited manner to amend the injunctive relief provisions that would prevent Mylan from realizing the benefit of the settlement. The underlying findings of fact and conclusions of law set forth in the Opinion, other than in the first paragraph on page 93, would otherwise remain intact. For this reason, the requested modification should be approved by the Court under Rule 60(b)(5).

Further, under Federal Rule of Civil Procedure 60(b)(6), a district court may amend or modify a final judgment for "any other reason that justifies relief." *See Kirby Forest Indus., Inc. v. United States*, 467 U.S. 1, 18 (1984). The Agreement, which is expressly conditioned upon this Court's grant of the parties' joint Rule 60 motion, unquestionably constitutes a clear "reason that justifies relief" from the injunction provisions of the Final Judgment Order. *Tommy Hilfiger Licensing, Inc. v. Costco Cos., Inc.*, No. 99CIV3894-LMM-JCF, 2002 WL 31654958, at \*3 (S.D.N.Y. Nov. 25, 2002) (issuing "indicative ruling" whereby the court, upon remand, would vacate judgment in light of settlement conditioned upon vacatur of judgment); Order at 2, *Karl Storz Imaging, Inc. v. Pointe Conception Med., Inc.*, No. CV09-08070 GAF (C.D. Cal. Apr. 2, 2012), ECF No. 331 (issuing "indicative ruling" whereby the court, upon remand, would allow

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<sup>2</sup> *See, e.g., Pennwalt Corp. v. Plough, Inc.*, 676 F.2d 77, 80 (3d Cir. 1982) ("There is a strong judicial policy in favor of parties voluntarily settling lawsuits."); *State of N.J. Dept. of Env'tl. Prot. v. Gloucester Env'tl. Mgmt. Servs., Inc.*, 668 F. Supp. 404, 407 (D.N.J. 1987).

dismissal of all pending claims and counterclaims based on the parties' having reached a settlement agreement)<sup>3</sup>; *United States v. Rodriguez*, No. 98-362-12, 2010 WL 5093908, at \*3 (E.D. Pa. Dec. 13, 2010) (issuing "indicative ruling" whereby the court, upon remand, would grant defendant's Rule 60(b) motion).

## **II. Federal Rule of Civil Procedure 62.1 Authorizes an "Indicative Ruling" by this Court, to Be Given Effect Upon Remand from the Appellate Court.**

The need for modification of the Final Judgment Order has arisen while this Court is divested of jurisdiction in light of the pending appeal. Under these circumstances, Federal Rule of Civil Procedure 62.1, together with Federal Rule of Appellate Procedure 12.1, describe the procedure this Court should follow in entertaining a Rule 60(b) motion. *See Acoustic Techs., Inc. v. Itron, Inc.*, No. 2011-1315, 2011 WL 3893811, at \*1 (Fed. Cir. Sept. 6, 2011); FED. R. APP. P. 12.1, 2009 Advisory Committee Note (stating that Rule 12.1 "corresponds to Federal Rule of Civil Procedure 62.1"). Under Federal Rule of Civil Procedure 62.1(a), "[i]f a timely motion is made for relief that the court lacks authority to grant because of an appeal that has been docketed and is pending, the court may . . . state [] that it would grant the motion if the court of appeals remands for that purpose. . . ." FED. R. CIV. P. 62.1(a). If the court makes such a statement, then "[t]he movant must promptly notify the circuit clerk under Federal Rule of Appellate Procedure 12.1 if the district court states that it would grant the motion . . . ." FED. R. CIV. P. 62.1(b). On remand, "[t]he district court may decide the motion if the court of appeals remands for that purpose." FED. R. CIV. P. 62.1(c).

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<sup>3</sup> *See also Karl Storz Imaging, Inc. v. Pointe Conception Med., Inc.*, No. 2012-1001, 2012 WL 2884704, at \*1 (Fed. Cir. Jul. 16, 2012) (granting motion to remand in light of District Court's indicative ruling that, upon remand, it would vacate the underlying judgment based on the parties' settlement agreement).

The parties jointly request that the Court, consistent with this procedure, issue an Indicative Ruling to amend the Final Judgment Order and amend the injunction as applicable to Mylan. If and when the Court issues the requested ruling, the parties will jointly request that the Federal Circuit dismiss the pending appeal and remand the case to this Court to allow for modification of the Final Judgment Order to amend the injunction provisions therein relevant to Mylan. In the event that the Court refrains from entering an Indicative Ruling of the nature described herein, the parties' Agreement will not take effect and the parties will proceed with the currently pending appeal.

### **CONCLUSION**

For the reasons set forth above, the parties respectfully request that the Court issue an Indicative Ruling pursuant to Federal Rule of Civil Procedure 62.1 stating that the Court would enter an order modifying the Final Judgment Order and amending the injunctive relief provisions relevant to Mylan to allow permitted activities under the Agreement, were the Federal Circuit to remand the case for this purpose.

Respectfully submitted,

**MCCARTER & ENGLISH LLP**

*Attorneys for Plaintiffs Janssen Products, L.P.  
and Janssen Sciences Ireland UC*

By: /s/ John E. Flaherty

John E. Flaherty (jflaherty@mccarter.com)  
100 Mulberry Street  
Four Gateway Center  
Newark, New Jersey 07102  
Telephone: (973) 639-7903

**CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.**

*Attorneys for Defendants/Counterclaim-  
Plaintiffs Mylan Pharmaceuticals Inc. and  
Mylan Inc.*

By: /s/ Melissa E. Flax

James E. Cecchi  
(JCecchi@carellabyrne.com)  
Melissa E. Flax  
(mflax@carellabyrne.com)  
5 Becker Farm Road  
Roseland, New Jersey 07068-1739

Telephone: (973) 994-1700

Of Counsel

Gregory L. Diskant (gldiskant@pbwt.com)

Eugene M. Gelernter

(emgelernter@pbwt.com)

Steven A. Zalesin (sazalesin@pbwt.com)

Irena Royzman (iroyzman@pbwt.com)

**PATTERSON BELKNAP WEBB & TYLER LLP**

1133 Avenue of the Americas

New York, New York 10036

Telephone: (212) 336-2000

Of Counsel

William A. Rakoczy

(wrakoczy@rmmslegal.com)

Deanne M. Mazzochi

(dmazzochi@rmmslegal.com)

Amy D. Brody (abrody@rmmslegal.com)

Tara M. Raghavan

(traghavan@rmmslegal.com)

**RAKOCZY MOLINO MAZZOCHI SIWIK**

**LLP**

6 West Hubbard Street, Suite 500

Chicago, Illinois 60654

Telephone: (312) 222-6301

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